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No. 02-1007

IN THE
Supreme Court of the United States

DUKE UNIVERSITY,
Petitioner,

v.

JOHN M. J. MADEY,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether the Federal Circuit properly refused to create judicially a *per se* exemption from infringement liability for universities that use the patented inventions of others to conduct research.

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BRIEF FOR RESPONDENT IN OPPOSITION

INTRODUCTION

The Federal Circuit applied its long-standing precedent concerning the experimental use defense to patent infringement and properly rejected Duke University's argument that it was entitled, as a matter of law, to a *per se* royalty-free use of patented inventions to generate revenue for itself, solely because it is a nonprofit research institution. The court of appeals remanded what it characterized as a "unique patent infringement case" (Pet. App. 3a) – after an interlocutory appeal from a district court decision granting partial summary judgment based on its own overly expansive understanding of Federal Circuit law – so that the factual record could be developed under the proper standard. The Federal Circuit correctly applied well-settled legal principles to require a fact-sensitive determination before making a legal judgment.

Duke's use of the patented inventions was not "experimental use" for scientific study of the inventions themselves. Rather, Dr. Madey offered rebuttal evidence to prove that his laser inventions that are housed at Duke are used for broad-based research – in medicine, nuclear physics, spectroscopy, materials science, and semiconductor technology. As such, Duke's continuing regular use of Dr. Madey's inventions as part of the routine operation of its research facilities advanced Duke's business interests in obtaining tens of millions of dollars in federal grant monies, attracting world-class faculty and students, paying capital and administrative costs at the university, and developing new inventions that Duke intends to patent and license to others. In rejecting Duke's request for a broad-based exemption from the patent laws, the Federal Circuit simply applied well-settled common-law precedent. The court did not produce the cataclysmic change in patent law asserted by petitioner and its *amici*.

Duke offers a welter of policy arguments for revising the patent laws to favor research universities and to limit the rights of inventors and businesses who depend on the protection of the Patent Act. Those suggestions should not be addressed to this Court, but rather to Congress, which has considered similar policy proposals in the past but has not seen fit to adopt them. Supreme Court review of a Federal Circuit decision that is procedurally, factually, and legally correct is not the proper mechanism to establish fundamental changes to the patent system that Congress created by statute under authority of the Constitution. Indeed, the current system serves the public interest well, including dramatically increased earnings in recent years from patent royalties paid to research universities themselves and greater private sector support for expansion of research into new fields.

STATEMENT

Background of Dr. Madey's Invention

As a graduate student in physics at the California Institute of Technology, respondent John M. J. Madey conceived the invention of the free electron laser ("FEL"). As a research scientist in laser physics at Stanford University, he perfected the invention without university or government financing. Prior to that, all lasers had relied on some medium – *e.g.*, ruby, helium-neon gas, or argon ion – and the limitations associated with the medium to achieve the desired results. What Dr. Madey envisioned, and later accomplished, was a new form of laser where the medium is a pure beam of electrons. *See* Arthur L. Schawlow, *Twenty-Five Years of Lasers*, in *Yearbook of Science and the Future* 171, 184-85 (1987). Although he proved the validity of his insight in a demonstration using the Stanford superconducting accelerator, Dr. Madey was unable to obtain any university, government, or other funding to develop his invention. C.A. App. A3344.

Undertaking the personal expense and risk of patenting the invention himself, Dr. Madey then licensed the invention to AT&T, for use by its subsidiary Bell Laboratories to develop its potential. He used the patent royalties from his license agreement and other personal funds to build a prototype FEL. *Id.* at A1417-18. Once it was operational and its capabilities had been demonstrated, Dr. Madey was able to attract research sponsors – primarily the United States Department of Defense. He continued his ground-breaking research, participating in the creation of a major FEL facility in France and stimulating interest in FEL technology on a world-wide basis. With funds provided by the Army's Space and Missile Defense Command through a contract administered by the Los Alamos National Laboratory, Dr. Madey's prototype laser was modified and improved at Stanford and became the "Mark III FEL." *Id.* at A1417-18, A3344-45.

As his Defense Department funding increased, along with the importance of his work to the Nation's defense, Dr. Madey found himself in an unforeseen conflict with Stanford, an institution that had provided him with unparalleled opportunity and which he had served faithfully and enthusiastically. The issue was the amount of "overhead" extracted by Stanford (and not entirely atypical of other major research institutions at the time) from government research grants that Dr. Madey received to support his work. Finding that excessive overhead charges would preclude successful completion of his work with the allotted funds, Dr. Madey objected to Stanford's overhead charges. *Id.* at A1419. The ensuing debate prompted congressional hearings and a national reform of the handling of federal research funds that is honored to the current date.

Dr. Madey's Dispute With Duke

Seeking to pursue his research and fulfill his obligations to his government sponsors, Dr. Madey explored other locations for his research. He was actively recruited by Duke University, where the faculty committee that investigated his credentials noted that virtually everyone interviewed agreed that he was a scientist of Nobel prize caliber. C.A. App. A1880, A1885. Also of significant appeal to Duke was the fact that Dr. Madey enjoyed outside financial support for his research that could not be duplicated by anyone in the field.

Based upon the promises by Duke to allow him to develop and expand his research program, Dr. Madey agreed to transfer his research to Duke, in what was the largest academic transfer of scientific research equipment, personnel, and funding in U.S. history. *Id.* at A136. At Duke, Dr. Madey's success continued. He brought in more than $40 million in research grants and contracts at Duke. *Id.* at A139. The program was so successful that he had been granted a $1 million grant from the W. M. Keck Foundation and an additional $1.3 million from the United States government to expand the FEL laboratory ("FEL Lab") at Duke and its research programs. *Id.* at A140, A1749.

At the same time, funding for nuclear physics – the long-standing mainstay in the field of physics at Duke and elsewhere – was disappearing. Like many post-World War II physics departments, the senior members of the Department of Physics at Duke were predominantly nuclear physicists. Unexpectedly, at least from Dr. Madey's perspective, and without his knowledge, Duke revised the plans for expansion of the FEL Lab in a manner that sought to facilitate the use of the FEL Lab for Duke's own nuclear research projects and at the expense of the government-funded research that Dr. Madey was committed to pursue. *Id.* at A142-45, A1892-907. After Dr. Madey brought these developments to light, the granting agency forced Duke to revise its budget and to provide university funds to cover the additional costs of the laboratory expansion attributable to the nuclear program. *Id.* at A1747-49.

Duke went to extraordinary lengths to impose its will on Dr. Madey, including having him removed as Principal Investigator of his own federal research grant from the Office of Naval Research ("ONR") for medical FEL research (the "MFEL Grant"). *Id.* at A149. Duke purported to justify its action by contending that Dr. Madey's colleagues in the department had lost confidence in his leadership of the research program, because of his protest over the improper diversion of federal funds to benefit Duke's nuclear program. *Id.* at A148-50. He was replaced as Principal Investigator by an academic theorist in the field of nuclear physics with no qualifications in laser physics. *Id.* at A142, A149. Academic scientists and government officials agree that Duke's action in removing Dr. Madey as Principal Investigator on the MFEL Grant is without precedent in American academic history. *See* Affidavit of Dr. George A. Neece, C.A. App. A1448-49; Affidavit of Dr. M. J. Soileau, C.A. App. A1442-43.

Faced with the *de facto* conversion of his research program by Duke, including the Mark III FEL laser that he built and funded initially with his own funds, Dr. Madey was forced to seek a new location for his research. He is

currently a Professor in the Department of Astronomy and Physics at the University of Hawaii, where he is continuing his research. *Id.* at A150. At Duke, Dr. Madey had been awarded a contract by the Defense Department's Office of Nuclear Treaty Organizations for "remote sensing" using the capabilities of the Mark III FEL laser. *Id.* at A1556, A2114. This research is of enormous importance for national defense because it can, among other things, detect underground nuclear detonations on the other side of the world better than any existing technology. Duke had no one else capable of pursing this research, so it was allowed to go unattended while Duke pursued the research that would benefit its own institutional and business objectives. *Id.* at A1556-57, A1672-73, A1676-77.

After Duke removed Dr. Madey as Director of the FEL Lab and Principal Investigator on the MFEL Grant, he gave Duke written notice that it was infringing his patents. Nonetheless, Duke proceeded to make use of the lasers (and the patented inventions) for its own purposes in a multitude of ways, a number of which promise significant financial reward to Duke. *Id.* at A148-50, A1677-78.

It is undisputed that the patents at issue belong to Dr. Madey individually and never belonged to Stanford, Duke, or any other institution. The funds used to obtain the patents and achieve success with the inventions were private funds and not university funds. Although the inventions have yielded little income to Dr. Madey, the laser has been used successfully under license at Vanderbilt University for surgery on an otherwise inoperable brain tumor and was also the centerpiece of the United States' star wars defense plan, for which the government spent approximately $1.5 billion in the 1980s to build a high-powered version of the patented laser at White Sands, New Mexico. *Id.* at A1796, A1870. *See also* Jeff Hecht, *Laser Pioneers* 47 (rev. ed. 1992). The potential uses of FEL technology continue to multiply, including applications in spectroscopy, materials science, and semiconductor technology that have great commercial promise.

District Court Proceedings

In 1997, Dr. Madey filed suit against Duke University for, *inter alia*,[1] infringement of his two patents. C.A. App. A135. The first (U.S. Patent No. 4,641,103 ("the '103 patent")) is for a microwave electron gun that is used as an electron source for FELs and for other purposes. *Id.* at A97-107, A151-52. The second (U.S. Patent No. 5,130,994 ("the '994 patent")) is for the process or capacity of the Mark III FEL commonly referred to as "phase-locking." *Id.* at A110-30, A154-55.

The district court issued two rulings that became the subject of the appeal to the Federal Circuit. First, pursuant to Federal Rule of Civil Procedure 12(b)(1), the court partially dismissed for lack of jurisdiction Dr. Madey's claim for infringement by Duke of the '103 patent. Pet. App. 66a-70a, 95a-96a. The court assumed that federal funding of research in the FEL Lab through a grant from the ONR established, as a matter of law, that any uses of the patents for activities funded under the MFEL Grant were uses "for the United States" pursuant to 28 U.S.C. § 1498(a), which provides for jurisdiction in the U.S. Court of Federal Claims for a claim of patent infringement when the invention is "used or manufactured by or for the United States without license of the owner thereof." *See* Pet. App. 66a-67a. Based on those assumptions, the court concluded that it lacked jurisdiction to hear the portion of Dr. Madey's patent infringement claim that related to activities funded under the MFEL Grant. *Id.* at 67a, 69a-70a.

Second, the district court granted summary judgment to Duke on the remaining patent infringement claims on the

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[1] The other claims before the district court stemmed from Duke's actions in removing Dr. Madey from control over his research program at Duke, and include claims for patent infringement, breach of contract, conversion of personal property, misappropriation of business opportunities, and constructive fraud. C.A. App. A133-64. Only the patent infringement claims were before the Federal Circuit on appeal. The district court's summary of Dr. Madey's various legal claims is at Pet. App. 32a-37a, 58a-61a.

ground that all of Duke's uses of the patents are exempt from infringement liability under the experimental use defense. *Id.* at 31a-54a. The court opined that, for Dr. Madey "to overcome his burden of establishing actionable infringement in this case, he must establish that [Duke] has not used the equipment at issue 'solely for an experimental or other non-profit purpose.' More specifically, [Dr. Madey] must sufficiently establish that [Duke's] use of the patent had 'definite, cognizable, and not insubstantial commercial purposes.'" *Id.* at 41a (quoting 5 Donald S. Chisum, *Chisum on Patents* § 16.03[1] (2000), and *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984), respectively) (citation omitted). In that manner, the court shifted the burden of proof to Dr. Madey to disprove Duke's defense to a claim of infringement. As a substantive matter, the court defined the experimental use doctrine as applicable only when the alleged infringer is conducting experiments "with commercial intent." *Id.* at 41a, 44a. The court credited Duke's assertions that its uses were "to teach, research, and expand knowledge," *id.* at 43a, while rejecting Dr. Madey's arguments and evidence that Duke's broader uses of Dr. Madey's patents exceeded the proper scope of the experimental use defense. "Without more concrete evidence to rebut [Duke's] stated purpose with respect to its research in the FEL Lab, [Dr. Madey] has failed to meet [his] burden of establishing patent infringement by a preponderance of the evidence." *Id.* at 45a. The court also declined to exercise supplemental jurisdiction over Dr. Madey's state law claims and, because the patent claims were the basis for federal jurisdiction, dismissed the state law claims without prejudice. *Id.* at 53a-54a, 55a-56a.

The Federal Circuit Decision

The Federal Circuit reversed in relevant part. Pet. App. 1a-30a. First, on the jurisdictional ruling, the court of appeals reversed the dismissal for lack of jurisdiction on the '103 patent claim and remanded the issue to the district court because the evidence in the record was insufficient to show "the scope of the government's rights" or how "the

rights granted to the government encompass Duke's use [of the patented inventions]." *Id.* at 29a. Duke does not seek Supreme Court review of that portion of the Federal Circuit's decision.

Second, on the experimental use defense on which the district court had granted summary judgment for Duke, the Federal Circuit reversed. The court of appeals agreed with Dr. Madey that the district court had committed three errors with respect to the experimental use defense: (1) the district court improperly imposed the burden of proof on Dr. Madey, as plaintiff, rather than on Duke, as the party moving for summary judgment and as the party asserting a defense, *id.* at 21a, 22a-23a; (2) the district court had "applied an overly broad version of the very narrow experimental use defense inconsistent with our precedent," *id.* at 21a, 24a-26a; and (3) the district court had relied on "overly general" evidence that was "not indicative of the specific propositions and findings required by the experimental use defense," *id.* at 21a.

The Federal Circuit explained that the test for application of the experimental use defense for well over 100 years had been whether or not the use was "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." *Id.* at 26a. Noting that use of Dr. Madey's patents furthered Duke's legitimate business interests and that Duke "is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream," *id.* at 26a n.7, the court of appeals remanded the case to the district court for further proceedings.

REASONS FOR DENYING THE PETITION

The Federal Circuit applied well-settled precedent in rejecting Duke's assertion that universities are entitled to a *per se* rule exonerating them from patent infringement claims when their employees conduct experiments. In remanding for further factual development and trial on the merits, the court's interlocutory judgment was faithful to the narrow circumstances in which the judicially created experimental use defense has been applied to relieve an

infringer of a patent holder's congressionally created statutory patent protection. Duke's assertion that the Federal Circuit's ruling will "chill" university research is exaggerated and, in any event, more appropriately directed to Congress rather than this Court.

I. THE FEDERAL CIRCUIT'S DECISION RESTATES WELL-SETTLED LAW AND DOES NOT ALTER THE AVAILABILITY OF THE EXPERIMENTAL USE DEFENSE TO NONPROFIT RESEARCH INSTITUTIONS

The Patent Act does not contain a general exemption from patent infringement liability for research universities or other research organizations. Nothing in the language of the Patent Act allows for distinctions between classes of users in weighing whether or not unauthorized use constitutes infringement of a patent. *See* 35 U.S.C. § 271(a) ("*[W]hoever* without authority . . . uses . . . any patented invention . . . infringes the patent.") (emphasis added). When the Federal Circuit rejected Duke's efforts to transform the narrow experimental use defense into a *per se* general exemption allowing free use of patented inventions by nonprofit organizations, it did so on the basis of settled law defining the scope of the experimental use defense. That defense, when properly defined and factually justified, remains equally available to all users – commercial and nonprofit alike.

A. The Origins Of The Experimental Use Doctrine Established A Limited Exemption From Infringement Liability For Experimentation On The Patented Device Itself

The earliest expressions of what has been called the experimental use exception, by Justice Story in *dicta*, identify scientific study of the invention itself for the advancement of knowledge as the activity to be protected:

> Use or construction "merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects,"

Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).

"[F]or the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification." *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813).

Decades later, that explanation for the experimental use exception had not changed, as a leading circuit decision stated that "an experiment *with a patented article* for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee." *Poppenhusen v. Falke*, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (emphasis added).[2]

Those judicial descriptions of the doctrine were synthesized later in the nineteenth century by a treatise writer on patents, Professor William Robinson, who articulated the underlying principles behind protecting a patent and permitting a narrow exception for experiments conducted on the patented device: "The interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others," subject to a limited exception for certain types of experiments:

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[2] The term "experimental use" is also used in a different context in disputes regarding patentability of inventions. Section 102(b) of the Patent Act establishes a bar to patentability for inventions that have been in public use for more than one year. In this context, an experimental use doctrine evolved in recognition of the public benefits that would result from allowing inventors to experiment with their inventions before applying for patent protection. One commentator uses the term "inventor experimental use" for this doctrine and the term "third-party experimental use" in the infringement context. *See* Eyal H. Barash, Comment, *Experimental Uses, Patents, and Scientific Progress*, 91 Nw. U. L. Rev. 667, 667 (1997). The legal standards that have developed for the two uses of the term thus address the different concerns that exist for patentability and infringement. *See* 2 *Chisum on Patents* § 6.02[7]; *see also City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. (7 Otto) 126 (1877) (addressing "experimental use" in the context of patentability).

> [W]here it is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of an intellectual character in the promotion of the employer's knowledge or the relaxation afforded to his mind.

3 William C. Robinson, *The Law of Patents for Useful Inventions* § 898, at 55-56 (photo. reprint 1972) (1890) (footnote omitted). As Professor Robinson further noted: "[I]f the products of the experiment are . . . used for the convenience of the experimentor, or if the experiments are conducted with a view to adaptation of the invention to the experimentor's business, the acts of making or of use are violations of the rights of the inventor and infringements of his patent." *Id.* at 56, *quoted in Roche Prods.*, 733 F.2d at 862.

B. Modern Applications Of The Experimental Use Defense Have Retained Its Narrow Focus

Modern applications of the experimental use defense have continued to observe those limitations. For example, in *Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343 (Fed. Cir. 2000) (per curiam), the Federal Circuit explained that it has long construed the experimental use exception "very narrowly." *Id.* at 1349. In that case, the court of appeals rejected an experimental use defense based on the district court's findings that tests were performed "expressly for commercial purposes" to sell the infringer's competing machines to potential customers. *Id.* The court found unpersuasive the infringer's effort "to cloak these tests in the guise of scientific inquiry," because the tests were not conducted "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." *Id.* (internal quotation marks omitted).

The articulation and application of the experimental use defense in *Embrex* followed logically from the Federal Circuit's decision in *Roche Products*, in which the court rejected an experimental use defense because the use of

patented drug ingredients for development of a competing product was "for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." 733 F.2d at 863. The court was unpersuaded by public policy arguments in favor of an exemption for such activities. *Id.* As the court noted, the experimental use defense originated out of a common-sense notion that *de minimis* uses of a patented device through experimentation on the device itself should not rise to the level of actionable infringements. But "[i]t is no trifle in its economic effect on the parties even if the quantity used is small" when the "unlicensed experiments [are] conducted with a view to the adaption of the patented invention to the experimentor's business." *Id.* Such use "is a violation of the rights of the patentee to exclude others from using his patented invention." *Id.*

The holdings of those Federal Circuit decisions – on which the court below expressly relied – followed on a line of prior cases that had defined the narrow contours of the experimental use defense. *See, e.g., Deuterium Corp. v. United States*, 19 Cl. Ct. 624, 634 (1990) (governmental use "to explore the technical and economic feasibility of controlling and eliminating the hydrogen sulfide emissions" was infringing) (internal quotation marks omitted); *Douglas v. United States*, 181 U.S.P.Q. (BNA) 170, 177 (Ct. Cl. 1974) ("each use [of patented jet engine designs] was in keeping with the legitimate business of the using agency and served a valuable governmental and public purpose" and was infringing), *modified on other grounds*, 510 F.2d 364 (Ct. Cl. 1975) (per curiam).

Petitioner erroneously asserts that the Federal Circuit "overrode Congress' legislative judgment . . . by misapplying language from a wholly irrelevant case." Pet. 13 (citing *Pitcairn v. United States*, 547 F.2d 1106 (Ct. Cl. 1976) (per curiam)). That assertion is insupportable, because the experimental use defense has never been enacted or codified in any form by Congress; rather, it has only been a judicially recognized defense to avoid infringement liability in

a narrowly defined circumstance. Petitioner's criticism of the Federal Circuit's invocation of *Pitcairn* also misses the mark, because the Federal Circuit merely cited that case for a widely accepted proposition: that an infringer cannot invoke the experimental use defense for a "use in keeping with the legitimate business of the alleged infringer." Pet. App. 24a. In *Pitcairn*, the court rejected an experimental use defense for governmental tests of helicopters with patented features "for lifting ability, for the effect of vibration on installed equipment, flight speed and range, engine efficiency, and numerous other factors," all of which were intended uses that infringed the patents because they were "in keeping with the legitimate business of the using agency." 547 F.2d at 1125-26. *See also Embrex*, 216 F.3d at 1349; *Douglas*, 181 U.S.P.Q. at 177.

C. The Decision Below Consistently Applied Well-Settled Federal Circuit Precedent

The Federal Circuit stressed that it was applying those well-settled precedents to the facts of this case. "Our precedent, to which we are bound, continues to recognize the judicially created experimental use defense, however, in a very limited form." Pet. App. 21a. "[W]e . . . conclude the experimental use defense persists albeit in the very narrow form articulated by this court in *Embrex*, 216 F.3d at 1349, and in *Roche*, 733 F.2d at 863." *Id.* at 22a (parallel citations omitted). Indeed, the court of appeals determined that the principal flaw of the district court's analysis was its deviation from the binding precedent of *Embrex*, *Roche*, and *Pitcairn*. *Id.* at 25a.

The court of appeals stressed that the district court had erred in not conducting a "detailed analysis of the character, nature and effect of the use." *Id.* "The correct focus should not be on the non-profit status of Duke but on the legitimate business Duke is involved in and whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." *Id.* at 26a. Because the district court instead had focused on the kind

of institution that Duke is, rather than on the kind of uses to which it was putting Dr. Madey's inventions, the case needed to be remanded for further fact-finding.

The Federal Circuit's determination that a remand was necessary is unassailable, as the proper determination of experimental use – like that of infringement itself – is a question of fact. *Bai v. L&L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998). Here, such fact-finding is necessary to confirm whether Duke has made regular use of the patented inventions in the ordinary course of its business by operating the lasers for their intended purpose as light sources used to remove animal tissue, to make precise measurements for standards, to identify substances and their molecular structure, and other functions to which the patents are directed. These uses were not for experimental study of the lasers as such and how they operate, but were routine operations of the lasers for other existing research purposes. These uses include activities designed to enhance Duke's capabilities as a provider of fee-generating medical services, for research funded by federal agencies, for research or product testing for corporate sponsors, for general use in their research by interested faculty members or other researchers authorized by Duke, and for the development of inventions for which Duke intends to obtain its own patents.

Under the principles of well-settled law established by *Embrex*, *Roche*, and *Pitcairn*, Dr. Madey has a right to ascertain at trial whether Duke's uses of the patented inventions go beyond experimental use and to require that Duke prove that the use is not exempt from infringement liability. Duke did not experiment *on* the lasers or their operations; Duke experimented *with* the lasers for its own purposes and benefit. The Federal Circuit's remand to the district court to develop a complete factual record of the character, nature, and effect of Duke's uses of the patented inventions thus constitutes no change in the law governing the experimental use defense by nonprofit universities; it is

simply an application of settled law to the unique factual situation presented. Pet. App. 3a, 25a-26a.

D. Petitioner's Criticisms Of The Federal Circuit's Well-Settled Law Are Unpersuasive

In an effort to make the decision below appear to be an extravagant departure from precedent, rather than merely a fact-bound application of settled law, petitioner makes a number of assertions that do not withstand scrutiny.

First, Duke contends that "the Federal Circuit's formulation of the exception renders it an empty shell, unavailable to the very entities the exemption was intended to cover." Pet. 5. As a preliminary matter, the phrase "the very entities the exemption was intended to cover" underscores petitioner's misguided belief that the experimental use defense is an "exemption" from patent infringement liability that has been conferred on certain "entities," namely, research universities. Duke offers no authority for its sweeping assertion, which is completely antithetical to the development of the experimental use doctrine. In each of the early references to experimental use cited by petitioner (Pet. 9), the researcher involved was a solitary, philosophically minded individual, not an "entity," and what the court or commentator in each such case deemed worthy of protection from the reach of the Patent Act is philosophical inquiry with "the sole effect being of an intellectual character in the promotion of the [user's] knowledge or the relaxation afforded to his mind." Pet. 10-11 (quoting 3 Robinson, *Law of Patents* § 898, at 55-56).

Petitioner can point to no judicial authority that has ever accepted its extraordinary and over-broad assertion that the experimental use defense gives researchers in universities carte blanche to infringe on patents. Justice Story surely did not have in mind the transmogrification of a limited exception that inoculated a researcher's individual curiosity into a *per se* rule allowing a multi-billion dollar research institution to enjoy royalty-free use of inventions

created solely by the ingenuity and perseverance of an individual inventor.

Second, petitioner's contention that the Federal Circuit's decision deprives nonprofit organizations, but *not* commercial users, of the benefit of the experimental use doctrine is incorrect. The court of appeals rejected the idea that the "character, nature and effect of the use" of the patented invention could be determined by the tax exempt status *vel non* of the user. Pet. App. 25a. As the court below explained, the focus is on the "use" and whether it can truly be regarded as "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." *Id.* at 26a. A major manufacturing concern and a nonprofit university alike that limit exploration of a patented invention to "ascertaining the sufficiency of the machine to produce its described effects," *Whittemore*, 29 F. Cas. at 1121, will be entitled to rely on the experimental use defense. *See also Sawin*, 21 F. Cas. at 555 (experimentation exempt from infringement claim if "for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification"). However, use of the patented article as disclosed in the patent to develop other valuable processes or products *is* infringement, even if the infringing activity is conducted by a "nonprofit" research institution. Under the Patent Act, any use of a patented invention for such other purposes without authority would constitute infringement. The sole pertinent issue is the nature of the "use" and whether it somehow qualifies as "philosophical inquiry" rather than the actual "use" to which the patent was directed. In this case, the Federal Circuit ordered a remand to determine whether Duke used the patented inventions regularly as they were intended to be used, not to verify their utility, but rather to obtain the benefits of the patented use.

Third, there is no merit to Duke's contention (Pet. 5-6, 13) that the court below improperly rested its decision on *Pitcairn*'s firmly established legal principles. The Federal Circuit's paraphrase of language from *Pitcairn* that "use in

keeping with the legitimate business of the alleged infringer does not qualify for the experimental use defense" is both accurate and apposite. Pet. App. 24a. Duke was not studying the lasers to ascertain how they functioned; Duke was using the function of the patented invention for its own purposes as part of a major research facility designed, among other things, to facilitate technology transfer to the private sector and to advance the creation of university-industry partnerships in developing commercial applications from the scientific discoveries in the FEL Lab. In this fashion, and in its solicitation of research funds, government contracts, and other revenue-generating activities, Duke is a direct economic competitor with Dr. Madey and his FEL research program.

Under these circumstances, and given the district court's misunderstanding of the proper scope of the experimental use defense, the Federal Circuit properly concluded that the disputed facts regarding the "character, nature and effect" (*id.* at 25a) of Duke's use of the patented inventions needed to be fully developed in further proceedings before the district court.

II. THE PUBLIC INTEREST IN THE ADVANCEMENT OF KNOWLEDGE IS BETTER SERVED BY EXISTING LAW THAN BY JUDICIAL EXPANSION OF THE EXPERIMENTAL USE DEFENSE

There is no merit to petitioner's hyperbolic assertion that "the Federal Circuit's opinion threatens substantial delay, further commercialization of non-profit research, and even the complete cessation of certain research projects." Pet. 19. Nonprofit research universities continue to enjoy the benefits of the experimental use defense for all activities that are properly classified as "experimental use," which includes verification and replication of the results of the inventor, as well as study of the invention itself and how it works for purposes of scientific understanding and advancement of knowledge. Only when universities go beyond such activities – without obtaining a license or otherwise

respecting a patent holder's rights – does patent infringement become an issue.

A. Basic Research Is Unaffected By The Federal Circuit's Experimental Use Doctrine

It is untrue that basic scientific research will be impeded unless universities are given free access to increasingly specialized bits of knowledge that may be patented. *See* Pet. 16-18. A recent survey by academic researchers, who conducted extensive interviews with university researchers and technology transfer officers, attorneys in the field of intellectual property, government and trade association personnel, and representatives of the private sector, revealed that "almost none of our respondents reported worthwhile projects being stopped because of issues of access to [intellectual property] rights to research tools." Instead, the survey concluded, "[o]ur interviews reveal that university and industrial researchers have adopted 'working solutions' that allow their research to proceed."[3]

Indeed, Duke, like other major universities, is in the forefront of making its discoveries available to the public for both commercial and non-commercial purposes – with an active program of technology licensing to the private sector, extensive corporate sponsorships for research, and participation in mutually beneficial collaborations with industry. While none of this activity is in any way improper, it does serve to demonstrate how far removed Duke's interests are from the disinterested "philosophical experiment" of individual scientists interested only in the advancement of learning that gave rise to the experimental use defense. Even if it may once have made sense to presume that the interest of a major private university in scientific advancement was synonymous with the public interest, that is no

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[3] John P. Walsh, Ashish Arora & Wesley M. Cohen, *Working Through the Patent Problem*, Science, Feb. 14, 2003, at 1021 (excerpted from John P. Walsh, Ashish Arora & Wesley M. Cohen, *Patents in the Knowledge-Based Economy* (W.M. Cohen & S. Merrill eds., National Academy Press, Washington, D.C., publication pending)).

longer the case. *See* Suzanne T. Michel, *The Experimental Use Exception to Infringement Applied to Federally Funded Inventions*, 7 High Tech. L.J. 369, 380-81 (1992) ("the gap between basic research and commercial interest has 'dramatically narrowed'"). Seeking financial resources dominates academia as much as it does the private sector. Indeed, the line between them is greatly blurred and cannot provide a principled basis for a legal rule as to when infringement of inventions is permitted.

As a result of Duke's extensive activities in developing new technologies and ensuring that its own inventions receive the protections of the patent laws, it has an extensive cadre of administrators and numerous legal advisers, from in-house counsel to prominent law firms, guiding Duke on how to maximize the financial rewards from its research. In 2001, universities earned $1.26 billion from technology licensing. *See* Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 Law & Contemp. Probs. 289, 300 n.60 (Winter 2003), *available at* http://www.law.upenn.edu/fac/akrai/lcp.update.922.doc. Those same resources surely can be applied to developing lawful ways of using the patented devices of other inventors rather than simply expropriating them.

B. Duke Seeks To Impose A Double Standard That Harms Entrepreneurial Efforts While Giving Universities A Windfall On The Use Of Patented Inventions

Apart from the substantial question of why a well-endowed and successful research institution should be entitled to free use of inventions that competing small businesses or individual users must negotiate for, and pay for, in the marketplace, there is no reason to assume that such government-compelled largesse will actually benefit the public, as Duke incorrectly asserts (Pet. 18-25). Major universities have become substantial competitors in the battle to achieve dominance and financial success in new scientific markets. That development may be a positive one, but it should not be confused with an altruistic search for the

truth that needs to be subsidized by America's inventors and entrepreneurs. Nothing in petitioner's view of the law obligates Duke to share freely with others the results of the research that *it* is undertaking with use of inventions patented by others. Duke, like other research institutions, will itself patent and control any discoveries that it makes through use of Dr. Madey's inventions for Duke's own private benefit.

A significant portion of the major advances in developing high-tech products and services has been made by relatively small companies. To attract the capital necessary to make such ventures successful, entrepreneurs need the protection provided by the Patent Act to keep powerful competitors, like Duke and other major research institutions, from simply appropriating these entrepreneurs' inventions for their own purposes. Michel, *The Experimental Use Exception*, 7 High Tech. L.J. at 381, 391, 396-97. Indeed, substantial policy concerns militate against granting academic departments the power to control the rate of progress in the advancement of new fields of scientific discovery. Increased support for basic scientific research and academic-commercial collaboration to deliver the promise of those discoveries to the world need not be financed by the expropriation of small inventors' patent rights. Commentators have noted the dangers in disrupting the prevailing patent regime:

> Changes in the patent laws that . . . exempt research activities from infringement liability could have a significant effect on the ability of these firms to raise funds for research. Given that overall private investment in biomedical R&D today exceeds public funding, the strong belief of private sector investors that patents are essential to their profit expectations urges caution in changing the underlying legal rules that support these investments.

Rai & Eisenberg, *Bayh-Dole Reform*, 66 Law & Contemp. Probs. at 299.

The Federal Circuit's decision in this case did not cause the growing trend toward commercialization of academic research. Nor would a contrary result in this case have any noticeable impact on the increasing desire of universities and commercial interests to collaborate in research endeavors. The forces driving that convergence, in both the academic and the private sector, remain powerful. On the academic side, operating costs for universities have increased with expanding numbers of scientists attracted to new and diverse fields, while government spending to support university research has not increased. *See* Michel, *The Experimental Use Exception*, 7 High Tech. L.J. at 379 n.57, 380. *See also* Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L. Rev. 1, 33 & n.166 (2001). At the same time, private industry wants to avoid investing the capital and other resources needed to maintain the infrastructure for broad scientific research, and yet private firms are increasingly vulnerable to scientific advances by competitors that may be financially devastating. *See* Michel, *The Experimental Use Exception*, 7 High Tech. L.J. at 381. The trend toward collaboration undoubtedly will continue, particularly if budget constraints force reduced federal spending on scientific research.

C. Duke's Contention That The Federal Circuit Decision Upsets Settled Expectations Has No Merit

Duke complains that the Federal Circuit's adherence to existing settled limits on the scope of the experimental use defense deprives university researchers of the "universal assumption" (Pet. 18) that they were exempt from the patent laws, thereby producing uncertainty and inadvertent patent violations. That argument not only is at odds with the facts of this case – Duke is knowledgeable of patent obligations in general and was given advance written notice of its infringing activities – but also grossly overstates the impact of the Federal Circuit's ruling regarding Duke's

actions. The experimental use defense is a common law doctrine derived from existing court decisions. No reasonable reliance can be placed on that doctrine by any interested party without careful analysis of the facts and circumstances under which the person plans to make use of a patented invention. The obligation to make an appropriate evaluation of the "character, nature and effect" (Pet. App. 25a) of any proposed use of a patented invention predated the decision in this case. It remains possible for university researchers to enjoy the benefit of the experimental use defense so long as they confine their activities to strictly experimental use in the forms recognized by the Federal Circuit and other courts. On the other hand, as universities pursue more and more research directed at achieving commercial success rather than satisfying philosophical curiosity, they will be obligated to honor the requirements of the patent laws and may therefore be unable to establish that they qualify for the experimental use defense. That obligation derives from the change in the nature and objectives of the universities' research and not from any change in the law. *See* Michel, *The Experimental Use Exception*, 7 High Tech. L.J. at 377 ("It is through the universities' own attempts to monopolize research results and collaborate with the commercial sector that they have potentially lost claim to the experimental use exception.").

Whatever uncertainty exists in the current system results from the variability of fact-intensive inquiries, as contrasted with *per se* bright-line rules. *Cf. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831 (2002) (rejecting a bright-line rule for the application of prosecution history estoppel to the doctrine of equivalents). In any event, the prevailing incentives (including extra-legal rewards of scientific and professional recognition) have been sufficient to fuel a boom in scientific research and a flood of patents by research universities. *See* Michel, *The Experimental Use Exception*, 7 High Tech. L.J. at 400 & nn.159-161; Mueller, *No "Dilettante Affair,"* 76 Wash. L. Rev. at 34-35 & n.177. Petitioner acknowledges the unprec-

edented advances flowing from the patented Cohen-Boyer discoveries in gene cloning. *See* Pet. 18. The widespread use of those discoveries was made possible by a far-sighted licensing policy adopted by the inventors. Duke worries that other inventors may not follow the Cohen-Boyer model and may adopt more restrictive licensing policies that would require it to engage in negotiations for patent rights. Duke suggests that it should not be required to make such accommodations in planning its research and that it and other research universities may be unable to handle the demands of marketplace negotiations for patent rights related to their research operations. Pet. 18-19. Experience to date indicates that Duke is wrong and that patent holders will indeed want to participate in additional scientific explorations that may yield vastly increased demand for their innovations.[4] What is not clear from Duke's argument is how the public interest would be served by shifting the power to decide what use is made of ground-breaking inventions away from the scientists who created them and into the hands of the technology managers running the highly competitive research operations at major universities.

Duke's real complaint is an objection to the patent system itself: "The possibility that the patent system could stifle or even stymie the progress of biotechnology and other important fields of research is both real and profound." Pet. 20. Duke essentially opposes the statutory monopoly given to inventors by Congress pursuant to the Constitution, on the grounds that it may limit useful research by others during the period of patent protection. Yet this is precisely the function exclusive patent rights were intended to perform:

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[4] A recent study estimates that, in 1995, licenses of patented inventions by universities produced $4.6 billion in investments and created 27,000 jobs in research and development toward commercialization of those university research results. *See* Peter B. Kramer, *et al.*, *Induced Investments and Jobs Produced by Exclusive Patent Licenses – a Confirmatory Study* (1997), *available at* http://www.autm.net/pubs/journal/97/5-97.html.

> A patent is a device to prevent the diffusion of new methods before the original investor has recovered profit adequate to induce the requisite investment. The justification of the patent system is that by slowing down the diffusion of technical progress it ensures that there will be more progress to diffuse. . . . Since it is rooted in contradiction, there can be no such thing as an ideally beneficial patent system, and it is bound to produce negative results in particular instances, impeding progress unnecessarily even if its general effect is favorable on balance.

Joan Robinson, *The Accumulation of Capital* 87 (1956), *quoted in* Michel, *The Experimental Use Exception*, 7 High Tech. L.J. at 409-10 (ellipsis in original).

To the extent patent law is intended to promote independent philosophical inquiry by thoughtful scientists, as the experimental use doctrine has traditionally been understood, it makes no sense to deprive the individual inventor of the benefits of his invention for the enrichment of university bureaucracies. In this case, Duke ignored the public interest and its obligations to the inventor and faculty member who made the university's success in this field possible. The Federal Circuit remanded the case for further proceedings to determine the rights of the parties based on the existing contours of a judicial doctrine that has been consistently applied since its original articulation nearly two hundred years ago. While Duke's desire to rewrite the law so that it may be exonerated from liability for its infringement is understandable, there is no public interest justification for such judicial intervention.

In any event, Duke's numerous policy arguments are better addressed to Congress, which can define by statute in the Patent Act the contours of any experimental use exception that is deemed both desirable for policy reasons and consistent with the Constitution's protections on a patent holder's rights. *See Infigen, Inc. v. Advanced Cell Tech., Inc.*, 65 F. Supp. 2d 967, 981 (W.D. Wis. 1999) ("[I]t is up to Congress to decide whether there should be an infringe-

ment exemption for university-based research laboratories. So far, Congress has not seen fit to grant one. *See, e.g.*, Patent Competitiveness and Technological Innovation Act of 1990, H.R. 5598, [101st] Cong. (1990), which was never passed but which, among other things, proposed exemptions from infringement liability for university research."). This Court should not accept petitioner's invitation to engage in a legislative function by engrafting onto the Patent Act an expansive exemption that departs from well-settled patent doctrine.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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